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By: _____

PATENT
Attorney Docket No. 018158-004990US
Client Ref. No. VX-1012 C3 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CARL F. KNOPP et al.

Application No.: 10/632,462

Filed: August 1, 2003

For: AUTOMATED LASER
WORKSTATION FOR HIGH
PRECISION SURGICAL AND
INDUSTRIAL INTERVENTIONS

Confirmation No. 3822

Examiner: David M. Shay

Technology Center/Art Unit: 3739

APPELLANTS' BRIEF UNDER
37 CFR §41.37

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Commissioner for Patents
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Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal electronically filed on March 31, 2006 for the above-referenced application, Appellants submit this Brief on Appeal.

1. REAL PARTY IN INTEREST

The real party in interest for the above-identified application is VISX, Incorporated, a Delaware corporation having its principal place of business at 3400 Central Expressway, Santa Clara, California 95051.

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2. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known that will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-15 are pending. Claim 3 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claims 1-5, 7, 9, 11, and 14 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Bille et al. U.S. Patent 4,848,340 ("Bille"). Claims 1-5, 7-9, 11-13 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Pflibsen et al. U.S. Patent 4,856,891 ("Pflibsen"). Claims 1-7, 9, 11, and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bille in view of Bille et al. U.S. Patent 4,901,718 ("the '718 patent"). Claims 10 and 15 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bille in combination with the '718 patent and further in view of Kohayakawa U.S. Patent 5,090,798 ("Kohayakawa"). Claims 1-15 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 43, 44, and 55-58 of U.S. Patent 6,299,307, claims 1-80 of U.S. Patent 6,099,522, claims 1-31 of U.S. Patent 5,865,832, claims 1-23 of U.S. Patent 5,966,157. Claims 1-15 also stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-9 and 27-34 of copending U.S. Patent Application No. 10/124,891.

4. STATUS OF AMENDMENTS

No amendments to the claims or the specification were made subsequent to the final rejection.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is generally directed to systems and methods that make use of a position of a natural tissue structure on the eye for stabilizing a beam of corneal ablation (or reshaping) treatment light energy against movements of the eye. (Appellants' Specification, p. 17, line 12 to p. 18, line 27.)

Appealed independent claim 1 is directed to a laser surgery system for treating a tissue located at a site of an eye. The system includes a laser making a beam of corneal ablation treatment light energy deliverable to the site so as to effect reshaping of a corneal tissue at the site. (*Id.*, p. 25, line 22 to p. 26, line 24.) An imaging system forms an image of a natural tissue structure on the eye that is in proximity to the site. (*Id.*, p. 28, line 21 to p. 29, line 5.) The image of the natural tissue structure is formed on a detector, which generates a first electrical signal in response to the image of the natural tissue structure related to a position of the structure. (*Id.*, p. 29, line 6 to p. 30, line 7.) A processor is adapted to generate a second electrical signal in response to the first electrical signal that stabilizes the beam of treatment light energy delivered to the tissue treatment site as the light energy is delivered to the tissue treatment site. (*Id.*, p. 30, lines 8-15.)

Similarly, appealed independent claim 11 is directed to a method of treating a tissue located at a site of an eye of a patient with a laser. A beam of a corneal reshaping treatment light energy is made with the laser and is deliverable to the tissue treatment site to treat a cornea. (*Id.*, p. 25, line 22 to p. 26, line 24.) A real-time image of the tissue treatment site (and a natural tissue structure in proximity to the tissue treatment site) is formed with an optical system. (*Id.*, p. 28, line 21 to p. 29, line 5.) A position of the natural tissue structure is measured from a first electrical signal, which is related to the position of the structure and is generated by a detector on which the image of the structure is formed. (*Id.*, p. 29, line 6 to p. 30, line 7.) A second electrical signal is generated in response to the measured position of the structure. The second electrical signal stabilizes the beam of treatment light energy as the treatment light energy is delivered to the tissue treatment site. (*Id.*, p. 30, lines 8-15.) The stabilized beam of treatment light energy is transmitted to the tissue treatment site so as to alter refraction of the cornea.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 3 is unpatentable under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which Appellants regard as the invention.

Whether claims 1-5, 7, 9, 11, and 14 are unpatentable under 35 U.S.C. §102(b) over Bille.

Whether claims 1-5, 7-9, 11-13 are unpatentable under 35 U.S.C. §102(b) over Pflibsen.

Whether claims 1-7, 9, 11, and 14 are unpatentable under 35 U.S.C. 103(a) over Bille in view of the '718 patent.

Whether claims 10 and 15 are unpatentable under 35 U.S.C. §103(a) as being unpatentable over Bille in combination with the '718 patent and further in view of Kohayakawa.

Whether claims 1-15 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 43, 44, and 55-58 of U.S. Patent 6,299,307, claims 1-80 of U.S. Patent 6,099,522, claims 1-31 of U.S. Patent 5,865,832, and claims 1-23 of U.S. Patent 5,966,157.

7. ARGUMENT

Claim 3 is Patentable under 35 U.S.C. §112, Second Paragraph

The final Office Action mailed December 2, 2005 ("Office Action") rejects claim 3 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention. In particular, the Office Action objects to the claim because it is allegedly "devoid of any structure and merely [appears] to be a statement of intended use [that] does not appear to limit the claim from which it depends." (Office Action, p. 2, lines 7-10.) Appellants respectfully submit that this rejection is erroneous and should be reversed.

In particular, Appellants note that an apparatus claim may include functional limitations that define the system by what it does, rather than what it is. (MPEP, §2173.05(g).) Functional language does not, in and of itself, render a claim improper and must be evaluated like any other limitation of the claim for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. (*Id.*) The separate requirement that an apparatus claim be distinguished from the prior art in terms of structure is not at issue. (*See*, MPEP, §2114.)

As such, Appellants submit that claim 3 clearly conveys to one of skill in the art further limitations on the system based on the function of the imaging system and the detector set forth in claim 1. In particular, claim 3 sets forth that the imaging system is configured to form an image of a limbal structure of the eye and that the detector is configured to generate a first electrical signal related to a position of the limbal structure in response to the image of the limbal structure formed on the detector.

Therefore, Appellants submit that claim 3 succeeds in particularly pointing out and distinctly claiming the subject matter of its functional limitations and is patentable under §112, second paragraph.

Claims 1-5, 7, 9, 11, and 14 are Patentable over Bille

The Office Action rejects claims 1-5, 7, 9, 11, and 14 under 35 U.S.C. §102(b) as allegedly being anticipated by Bille. Appellants respectfully submit that this rejection is erroneous and should be reversed.

Bille refers to an eyetracker for moving the path of a laser beam in response to patient eye movement. (Bille, Abstract.) In particular, Bille discloses that while the patient's eye is in reference alignment, the laser source is used to mark a grid on the cornea of the patient's eye to fix a known relationship between the grid and the eye's visual axis. (*Id.*, col. 2, lines 16-20.) The grid is made of a series of small incisions created in the cornea by the cutting laser. This artificially imposed grid is then used as an optical reference for the operation of the eyetracker. (*Id.*, col. 5, lines 20-44.)

Appellants submit that Bille fails to disclose “forming a real-time image of . . . a natural tissue structure with an optical system” and “measuring a position of the [natural] tissue structure from a first electrical signal generated by a detector, the detector having the image of the [natural tissue] structure formed thereon, the first signal being related to the position of the [natural tissue] structure,” as set forth by independent claim 11 (emphasis added).

Appellants further submit that Bille fails to disclose “an imaging system forming an image of a natural tissue structure” and “a detector having the image of the [natural tissue] structure formed thereon and generating a first electrical signal in response to the image of the

[natural tissue] structure, the first signal being related to a position of the [natural tissue] structure,” as set forth by independent claim 1 (emphasis added).

To properly establish *prima facie* anticipation, every element of the claims must be shown in a single reference. (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP, §2131.) Significant and advantageous elements of Appellants’ claimed invention are absent from the cited Bille reference.

In particular, Bille fails to show or suggest Appellants’ system and method for detecting a natural tissue structure on the eye and generating an electrical signal related to the position of the natural tissue structure to stabilize the beam of treatment light energy. Appellants’ novel system and method are advantageous at least because they utilize existing natural tissue structures on the eye to create a reference position for laser operation. To the contrary, Bille teaches that a grid of artificial incisions must be cut into the cornea so that its eyetracker may detect the position of the incisions and ascertain a reference position of the eye. (Bille, col. 5, lines 20-44.) Therefore, it should be clear that Appellants’ claimed non-invasive approach constitutes a patentable advance over the approach described by Bille, and is neither taught nor suggested by Bille.

Accordingly, independent claims 1 and 11 are patentable over Bille at least because the reference fails to show or suggest all the features of each claim. Claims 2-5, 7, 9, and 14 are patentable over Bille at least because they depend from claims 1 and 11.

Claims 1-5, 7-9, 11-13 are Patentable over Pflibsen

The Office Action rejects claims 1-5, 7-9, and 11-13 under 35 U.S.C. §102(b) as being anticipated by Pflibsen. Appellants respectfully submit that this rejection is erroneous and should be reversed.

Pflibsen refers to an eye movement tracker for stabilizing an ophthalmic illumination on the opaque fundus at the back of the eye (emphasis added) (Pflibsen, Abstract). A tracking strip of light is projected onto the fundus so that the light from the fundus produces a reflected tracking strip on a detecting element. (*Id.*, col. 2, lines 25-35.) The intensity profile of the image strip is continuously scanned and analyzed to provide correction signals to direct the

optical path of an additional diagnostic beam to a fixed position on the opaque fundus structure.
(*Id.*, col. 2, lines 25-35.)

Appellants submit that Pflibsen fails to disclose “making a beam of a corneal reshaping treatment light energy with the laser,” “generating a second electrical signal in response to the measured position of the [natural tissue] structure, the second signal stabilizing the beam of [the corneal reshaping] treatment light energy as the treatment light energy is delivered to the tissue treatment site,” and “transmitting the stabilized beam of [the corneal reshaping] treatment light energy to the tissue treatment site so as to alter refraction of the cornea,” as set forth by independent claim 11 (emphasis added).

Appellants further submit that Pflibsen fails to disclose “a laser making a beam of a treatment light energy, the treatment light energy comprising corneal ablation light energy deliverable to the site so as to effect reshaping of a corneal tissue at the site” and “a processor adapted to generate a second electrical signal in response to the first electrical signal [related to a position of the natural tissue structure], the second signal stabilizing the beam of treatment light energy delivered to the tissue treatment site as the light energy is delivered to the tissue treatment site,” as set forth by independent claim 1 (emphasis added).

To properly establish *prima facie* anticipation, every element of the claims must be shown in a single reference. (*Verdegaal Bros.*, 814 F.2d at 631; MPEP, §2131.) Significant and advantageous elements of Appellants’ claimed invention are absent from the cited Pflibsen reference.

In particular, Pflibsen fails to show or suggest Appellants’ claimed system and method for stabilizing a beam of corneal ablation or reshaping light energy as the light energy is delivered to the treatment site to alter the refraction of the optically transparent cornea or effect reshaping of the clear corneal tissue. Rather, Pflibsen is solely directed to stabilizing a diagnostic beam onto the opaque fundus of the eye. The non-trivial difference between Appellants’ approach for stabilizing an ablation/reshaping beam onto the clear cornea of the eye (using a natural tissue structure located proximal to the treatment site) and the teaching of Pflibsen is demonstrated by the very different nature of the structures being tracked. While stabilization with reference to an opaque moving object at the back of the eye may be sufficient

for fixing a diagnostic beam onto the fundus of the eye, the flexibility of the eye indicates such stabilization may well be inadequate for carrying out ablation or reshaping on the clear cornea located at the front of the eye. Therefore, it should be clear that Appellants' claimed system and method for making, stabilizing, and delivering a beam of corneal ablation/reshaping light energy is not taught or suggested by Pflibsen.

Accordingly, independent claims 1 and 11 are patentable over Pflibsen at least because the reference fails to disclose all the features of each claim. Claims 2-5, 7-9, 12, and 13 are patentable over Pflibsen at least because they depend from claims 1 and 11.

Claims 1-7, 9, 11, and 14 are Patentable over Bille and the '718 Patent

The Office Action rejects claims 1-7, 9, 11, and 14 under 35 U.S.C. §103(a) as allegedly being obvious from Bille in view of the '718 patent. Appellants respectfully submit that this rejection is erroneous and should be reversed.

As previously discussed, Bille refers to an eyetracker in which a grid of small incisions are made on the cornea of the patient's eye to enable tracking against patient eye movement.

The '718 patent refers to a laser beam guidance system that moves and focuses a laser beam in accordance with a preestablished program to photochemically affect cells in the cornea of the eye. ('718 patent, Abstract.)

To properly establish *prima facie* obviousness under 35 U.S.C. §103, three basic requirements must be met: 1) There must be some suggestion or motivation, either in the references themselves, in the knowledge generally available to one of ordinary skill in the art, or in the nature of the problem to be solved, to modify the reference or to combine reference teachings (*In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998)); 2) there must be a reasonable expectation of success (*In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986)); and 3) the prior art reference(s) must teach or suggest all the claim limitations (*In re Royka*, 490 F.2d 981 (CCPA 1974)).

Appellants submit that the rejection is erroneous because even the alleged combination of references fails to show or suggest all the features of Appellants' claims. In

particular, Appellants have demonstrated in the foregoing that Bille fails to disclose a system or method for detecting a natural tissue structure on the eye and generating an electrical signal related to the position of the natural tissue structure to stabilize the beam of treatment light energy. As the '718 patent merely refers to a system for programmably controlling a laser without reference to detection of natural tissue structures, it fails to cure this deficiency in Bille.

Therefore, independent claims 1 and 11 are patentable over Bille and the '718 patent at least because neither reference discloses Appellants' claimed system and method for detecting the position of a natural tissue structure and using the position to stabilize a beam of treatment light energy. Claims 2-7, 9, and 14 are patentable over both references at least because they depend from claims 1 and 11.

Claims 10 and 15 are Patentable over Bille, the '718 patent, and Kohayakawa

The Office Action rejects claims 10 and 15 under 35 U.S.C. §103(a) as allegedly being unpatentable over Bille in combination with the '718 patent and further in view of Kohayakawa.

To properly establish *prima facie* obviousness under 35 U.S.C. §103, three basic requirements must be met: 1) There must be some suggestion or motivation, either in the references themselves, in the knowledge generally available to one of ordinary skill in the art, or in the nature of the problem to be solved, to modify the reference or to combine reference teachings (*In re Rouffet*, 149 F.3d at 1357); 2) there must be a reasonable expectation of success (*In re Merck & Co., Inc.*, 800 F.2d at 1091); and 3) the prior art reference(s) must teach or suggest all the claim limitations (*In re Royka*, 490 F.2d at 981).

Appellants respectfully submit that this rejection is erroneous for at least the same reasons set forth in the foregoing with respect to the nonobviousness of independent claims 1 and 11, from which claims 10 and 15 respectively depend. Moreover, the '718 patent and Kohayakawa, whether taken alone or in combination, fail to remedy the failings of Bille set forth in the foregoing. Therefore, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071 (Fed. Cir.)) Accordingly, Appellants respectfully request that this rejection be reversed.

Claims 1-15 are Patentable under the Judicially Created Doctrine of
Obviousness-Type Double Patenting

The Office Action rejects claims 1-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43, 44, and 55-58 of U.S. Patent 6,299,307, claims 1-80 of U.S. Patent 6,099,522, claims 1-31 of U.S. Patent 5,865,832, and claims 1-23 of U.S. Patent 5,966,157.

Appellants submit herewith Terminal Disclaimers obviating the rejections based on U.S. Patents 6,299,307, 6,099,522, and 5,865,832.

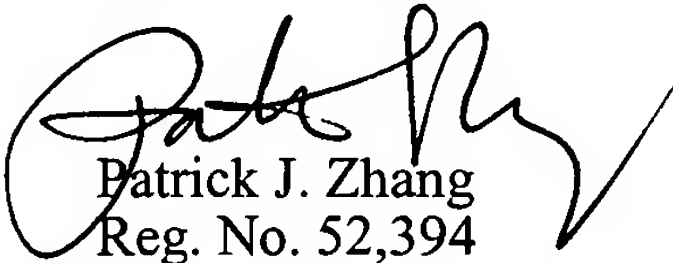
Appellants respectfully submit that the rejection based on U.S. Patent 5,966,157 is erroneous and should be reversed.

In particular, Appellants note that U.S. Patent 5,966,157 to Dolan has eight claims directed to a method for cleaning a print apparatus. Appellants submit that the rejection based on the '157 patent was made in error as none of its claims render obvious Appellants' claims directed to a system and method for treating eye tissue. Accordingly, Appellants respectfully request that this rejection be reversed.

8. CONCLUSION

For at least these reasons, it is respectfully requested that the above-identified rejections be reversed.

Respectfully submitted,


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9. CLAIMS APPENDIX

1. A laser surgery system for treating a tissue located at a site of an eye, the system comprising:

a laser making a beam of a treatment light energy, the treatment light energy comprising corneal ablation light energy deliverable to the site so as to effect reshaping of a corneal tissue at the site;

an imaging system forming an image of a natural tissue structure, the natural tissue structure being in proximity to the site, the image of the site being visible to the user;

a detector having the image of the structure formed thereon and generating a first electrical signal in response to the image of the structure, the first signal being related to a position of the structure; and

a processor adapted to generate a second electrical signal in response to the first electrical signal, the second signal stabilizing the beam of treatment light energy delivered to the tissue treatment site as the light energy is delivered to the tissue treatment site.

2. The system of claim 1 wherein the imaging system forms a real time image of the tissue treatment site, and the second signal stabilizes the real time image of the tissue treatment site as seen by the user.

3. The system of claim 1 wherein the structure corresponds to a limbal structure of the eye, and wherein the detector generates the first electrical signal in response to the image of the limbal structure.

4. The system of claim 1 wherein at least one processor comprises a computer program adapted to control a delivery of the light energy to the tissue treatment site in response to at least one action of the user.

5. The system of claim 1 wherein the processor comprises a central processing unit and a computer program adapted to determine the position of the structure.

6. The system of claim 1 wherein the processor comprises an analog circuit measuring a position of the structure.

7. The system of claim 2 further comprising a display visible to the user, the display showing the stabilized real time image of the site.

8. The system of claim 7 wherein the image of the site is formed on a camera, the camera being electronically coupled to the display.

9. The system of claim 1 wherein the optical system further comprises a movable mirror, and the movable mirror moves in response to the second signal.

10. The system of claim 1 further comprising:

optical path means for receiving the laser beam, for aiming the beam at a position in X-Y directions transverse to the beam, and for focusing the beam at a distance in a Z direction as desired toward the tissue treatment site;

beam steering means connected to the optical path means for controlling the position at which the beam is aimed in X-Y directions;

beam focusing means connected to the optical path means for controlling the distance at which the laser beam is focused;

tracking means for tracking eye movements during the progress of the surgery, including X-Y tracking means for tracking the structure of the eye in X and Y directions, and Z tracking means for tracking movements of the eye in the Z direction toward and away from the system; and

safety interrupt means for interrupting delivery of the laser beam to the patient when it is determined that the tracking means has lost the structure being tracked.

11. A method of treating a tissue located at a site of an eye of a patient with a laser, the tissue treatment site being seen by a user, the method comprising:

making a beam of a corneal reshaping treatment light energy with the laser, the treatment light energy being deliverable to the tissue treatment site so as to treat a cornea;

forming a real-time image of the tissue treatment site and an image of a natural tissue structure with an optical system, the natural tissue structure being in proximity to the tissue treatment site;

measuring a position of the tissue structure from a first electrical signal generated by a detector, the detector having the image of the structure formed thereon, the first signal being related to the position of the structure;

generating a second electrical signal in response to the measured position of the structure, the second signal stabilizing the beam of treatment light energy as the treatment light energy is delivered to the tissue treatment site; and

transmitting the stabilized beam of treatment light energy to the tissue treatment site so as to alter refraction of the cornea.

12. The method of claim 11 further comprising stabilizing a real time image of the tissue treatment site as seen by the user while the treatment light energy is delivered to the tissue treatment site.

13. The method of claim 12 further comprising moving a mirror in response to the second signal to stabilize the real-time image of the site as seen by the user.

14. The method of claim 11 further comprising ablating a surface of the cornea of the eye by pulsing the laser.

15. The method of claim 11 further comprising:

receiving the beam with an optical delivery system;

aiming the beam at a position in X-Y directions transverse to the beam with the optical delivery system, the optical delivery system comprising a beam steering optic;

focusing the beam in a Z direction at a distance with the optical delivery system, the optical delivery system comprising a front lens element;

controlling the position at which the beam is aimed in X-Y directions using the beam steering optic of the optical delivery system;

controlling the distance at which the laser beam is focused in the Z direction with the beam focusing optic of the optical delivery system;

tracking eye movements of the patient during the progress of the surgery by tracking eye movements in X and Y directions with the detector and by tracking eye movements in a Z direction with a second optical detector;

automatically shifting the beam steering optic and the beam focusing optic with a processor as the eye is tracked through X, Y and Z directions to change the position of the laser beam and the distance at which the laser beam is focused so as to follow movements of the eye;

and

automatically interrupting delivery of the laser beam to the tissue treatment site when it is determined via the processor that the sensor has lost the structure being tracked.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.